University of Lisbon

Faculty of Dental Medicine

Influence of splinting materials (auto vs. photopolymerizing) on implant impression accuracy: An *in vitro* study

Luís Miguel Baptista Braz

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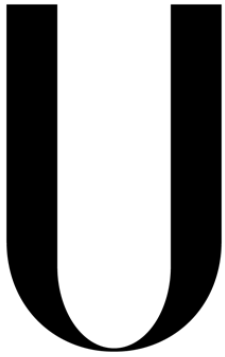

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Dissertation supervised by

Professor Doutor João Caramês
Prof. Doutora Helena Francisco

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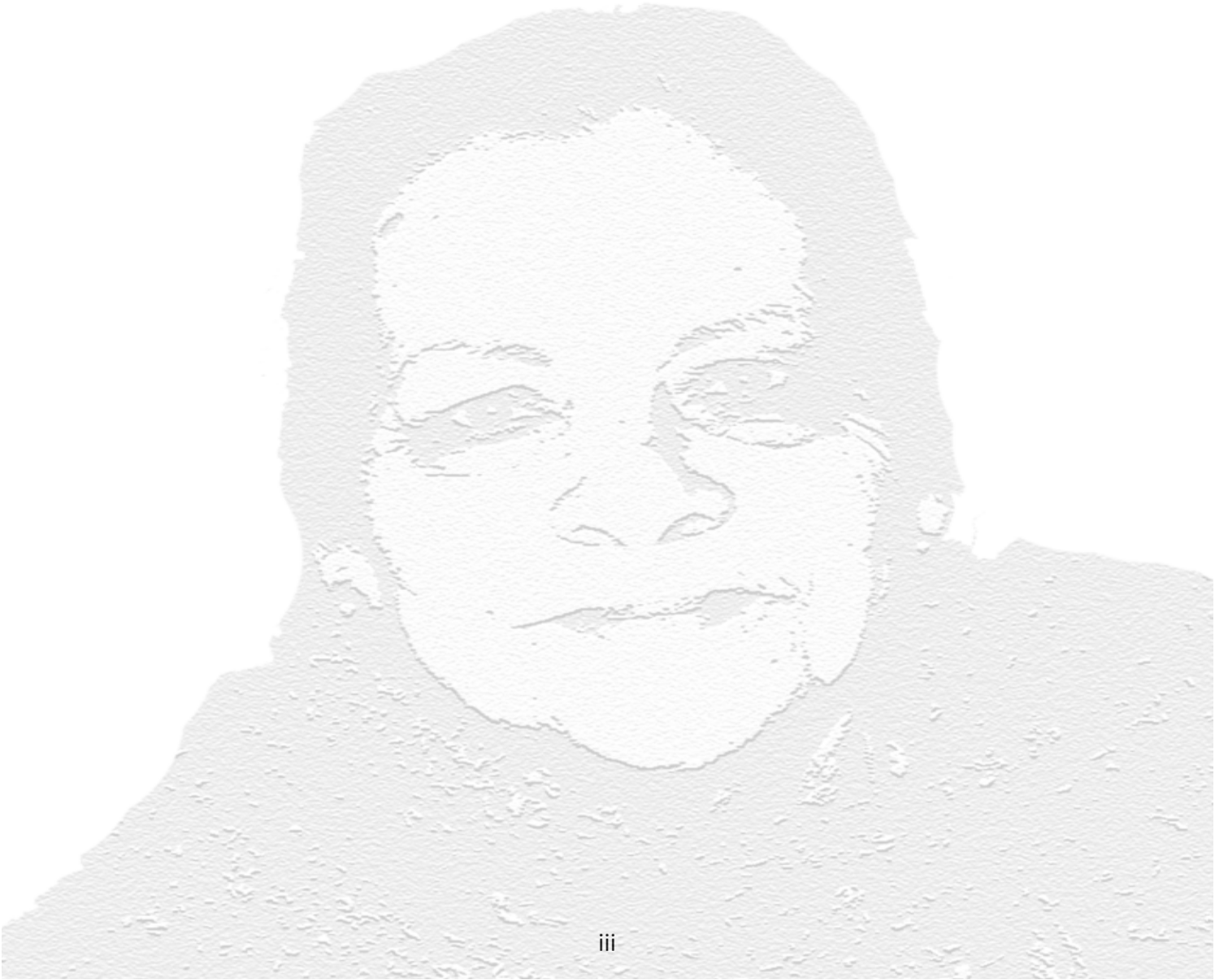
In memory of my beloved grandmother Noémia,

Despite the enormous sorrow that I have for you not be able to witness this moment, I hope the sadness caused by your departure is mitigated by the pride that you may be feeling at this time.



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Abbreviations

PMMA	Polymethyl Methacrylate
PE	Polyether
PVS	Polyvinyl Siloxane
IC	Internal Connection
EC	External Connection

Abstract

Purpose: The aim of the present study was to evaluate if there was any significant difference in accuracy between multiple-unit dental implant casts obtained from splinted direct impression techniques using 2 splinting materials by comparing the casts to the reference models. The null hypothesis tested was that the accuracy of implant-impressions was not affected regardless of the splinting material used.

Materials and Methods: One master model was fabricated with polyurethane by duplicating an edentulous mandibular arch. Four implant analogs (Biomet 3i®, Florida, USA- external connection) were placed in the intra-mental foramen region, simulating a supra osseous clinical environment and with longitudinal axis parallel to each other. The replicas were numbered anti-clockwise from 1 to 4 based on a frontal view of the master cast. Reference bars machined to fit passively were fabricated using cobalt-chromium alloy. The implant copings were splinted, after the appliance of a matrix of dental floss (ACCLEAN®, Henry Schein®, New York, USA), with CONLIGHT photopolymerizing composite (Conlight; Kuss Dental, Madrid, Spain) **(Group A**) and GC acrylic resin (GC pattern™; GC Corp, Tokyo, Japan) **(Group B)**, twenty impressions were obtained - ten for each group - in accordance with manufacturer's directions using a two-step impression technique: Putty - consistency vinyl polysiloxane (Panasil® Putty Soft, Kettenbach®, Eschenburg, Germany) was used as a tray material combinated with light-consistency vinyl polysiloxane (Panasil® Initial Contact Light, Kettenbach®, Eschenburg, Germany). Each cast produced was assessed for accuracy by attaching the respective reference framework with a single screw on analog number 1 and measuring the vertical gap between each cylinder and the respective analog (2, 3 or 4) at four different points - buccal, lingual, distal and mesial – using a toolmaker's microscope.

Results: The results showed there were significant differences between **Group A** (photopolymerizing composite) and **Group B** (PMMA autopolymerizing resin), comparing measurements in all analog/ point combinations. It was determined that in **Group B** the vertical gaps were statistically higher than the ones verified in **Group A**.

Conclusions: The results of this study suggest that implant impressions splinted with photopolymerizing composite (Conlight; Kuss Dental, Madrid, Spain) presents better results on the accuracy comparing to implant impressions splinted with PMMA autopolymerizing acrylic resin (GC pattern™; GC Corp, Tokyo, Japan). Implant-level impressions made with PMMA autopolymerizing splinted resin resulted in statistically lower accuracy than the ones made in the photopolymerizing composite group.

Keywords: Passive Fit, Splinting, Impression accuracy, PMMA autopolymerizing acrylic resin, Photopolymerizing composite.

Resumo

A reabilitação oral de pacientes desdentados parciais ou totais com implantes dentários tem evidenciado, desde há vários anos, elevadas taxas de sucesso clínico, consistentemente suportadas pela literatura. A otimização deste sucesso está diretamente relacionada com a passividade da infra-estrutura protética quando aparafusada a múltiplos implantes.

A passividade de uma prótese total fixa sobre implantes não é totalmente alcançável devido às inúmeras variáveis envolvidas no processo de fabricação da mesma. Parece, no entanto, existir um certo nível de tolerância, sendo ainda desconhecido o grau de desadaptação da prótese em relação aos implantes que poderá conduzir a complicações tanto biológicas e/ou mecânicas.

Um dos passos que é considerado mais crítico para o sucesso a longo prazo de uma prótese implanto-suportada é a precisão das impressões obtidas, que pode ser influenciada por inúmeros fatores, tais como a técnica de impressão usada (moldeira aberta vs. moldeira fechada; ferulizar vs. não ferulizar), o material de impressão usado, o tipo de impressão realizada (convencional vs. digital), a angulação e o número de implantes.

Até à data, a influência do tipo de material de ferulização (fotopolimerizável vs. autopolimerizável) na precisão de impressões em implantes permanece pouco esclarecida. A informação existente na literatura sobre o desempenho deste fator, tanto *in vitro* como também *in vivo*, é escassa.

Objectivo: O objetivo do presente estudo laboratorial foi avaliar a possível existência de diferenças significativas entre a precisão de impressões à cabeça do implante usando dois materiais de ferulização diferentes, um compósito fotopolimerizável (Conlight; Kuss Dental, Madrid, Spain) e uma resina acrílica autopolimerizável (GC pattern™; GC Corp, Tokyo, Japan).

A hipótese nula testada foi: a precisão de impressões sobre implantes não é influenciada pelo tipo de material de ferulização, seja ele autopolimerizável ou fotopolimerizável.

Materiais e métodos: Foi obtido um modelo preliminar de gesso através da duplicação de uma arcada mandibular edêntula. Quatro buracos foram feitos bilateralmente, na região entre os foramens mentonianos, para a inserção de quatro

réplicas de conexão externa (Biomet 3i®, Florida, USA) com 4,10mm de diâmetro. As réplicas foram colocadas de modo a simular uma condição clínica supra-óssea, com eixos de inserção paralelos entre si e fixadas com cera para permitir a sua remoção após a fabricação da barra de referência.

Sobre as réplicas, foram colocados cilindros de fundição correspondentes e unidos com cera, para posteriormente ser fundida uma barra de referência em crómio cobalto.

Com o objetivo de garantir uma completa passividade, as réplicas foram aparafusadas à barra de referência e, desta forma, reinseridas nos buracos do modelo preliminar. Para produzir o modelo final, foi feita uma matriz de silicone de condensação (Zetalabor; Zhermack®, Badia Polesina, Italy) sobre o respectivo modelo de gesso com a respetiva barra aparafusada e corrida a poliuretano (Sherapolan 2:1; Shera®, Lemförde, Germany) e, as réplicas foram numeradas de 1 a 4 no sentido anti-horário, baseado numa vista frontal do modelo.

Para a realização do procedimento de impressão, foram utilizadas moldeiras standard, devidamente perfuradas para a técnica de moldeira aberta, sobre as quais foi aplicado um adesivo para polivinilsiloxano (Panasil® Adhesive, Kettenbach®, Eschenburg, Germany).

Os análogos dos implantes foram ferulizados com uma matriz de fio dentário (ACCLEAN®, Henry Schein®, New York, USA). No Grupo A, os análogos foram depois ferulizados com um compósito fotopolimerizável (Conlight; Kuss Dental, Madrid, Spain). No Grupo B, os análogos foram depois ferulizados com uma resina acrílica autopolimerizável (GC pattern™; GC Corp, Tokyo, Japan).

Foi realizado, para este estudo, um total de 20 impressões – 10 impressões para cada grupo – utilizando uma técnica de impressão de 2 passos, de acordo com as indicações do fabricante: polivinilsiloxano de consistência putty (Panasil® Putty Soft, Kettenbach®, Eschenburg, Germany) colocado na moldeira, e, polivinilsiloxano de consistência light (Panasil® Initial Contact Light, Kettenbach®, Eschenburg, Germany) injetado em volta das coifas de impressão para garantir a sua completa cobertura. A moldeira foi posicionada e mantida sob pressão manual durante 6 minutos. Em todas as impressões, foram utilizadas coifas de impressão (Biomet 3i®, Florida, USA) para a técnica de moldeira aberta.

As impressões foram corridas a gesso tipo IV (GC Fujirock EP®; GC Corp, Tokyo, Japan) misturado a vácuo e segundo as instruções do fabricante. Os modelos

obtidos foram mantidos a temperatura ambiente durante um período mínimo de 24 horas antes da realização das medições.

A avaliação da precisão de cada modelo foi feita aparafusando a respetiva barra de referência apenas na réplica número 1 e medindo a discrepância vertical através do uso de um microscópio comparador (Toolmakers Microscope, Mitutoyo). As medições foram efetuadas entre a base de cada cilindro da barra de referência e a respetiva réplica (2, 3 ou 4), em quatro pontos diferentes – vestibular, lingual, mesial e distal.

A análise estatística de resultados deste estudo foi realizada através do teste paramétrico T- student quando se verificou que a amostra seguia uma distribuição normal. Por outro lado, foi aplicado o teste não paramétrico Mann-Whitney quando esta condição não se verificou (Os testes de Kolmogorov-Smirnov e Shapiro-Wilk foram usados para avaliar se os resultados seguiam uma distribuição normal; o teste de Levene foi usado para determinar a igualdade de variâncias). O nível de significância estabelecido foi de 5%.

Resultados: Os resultados obtidos demonstraram existir diferenças significativas entre os grupos ao comparar as medições efetuadas para cada associação ponto/réplica específica. A análise estatística determinou que no Grupo B (autopolimerizável) as discrepâncias verticais observadas apresentaram valores estatisticamente superiores às do Grupo A (fotopolimerizável).

Conclusões: Tendo em conta as limitações deste estudo laboratorial, os resultados obtidos sugerem que impressões feitas à cabeça do implante usando como material de ferulização um compósito fotopolimerizável (Conlight; Kuss Dental, Madrid, Spain) apresentam melhores resultados na precisão de impressões quando comparados com impressões feitas com resina acrílica autopolimerizável (GC pattern™; GC Corp, Tokyo, Japan).

Estudos futuros poderão proceder à avaliação, comparação e análise de diferentes materiais usados para ferulizar impressões sobre implantes, no que diz respeito à sua influência na precisão de impressões. Além disso, seria também importante avaliar *in vivo* se os valores de discrepância vertical obtidos neste estudo são clinicamente significativos.

Palavras-chave: Ajuste Passivo, Ferulização, Precisão de impressões, Resina acrílica autopolimerizável, Compósito fotopolimerizável.

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I. Introduction

Osteointegrated implants have provided alternative treatments to conventional prostheses for patients who lost their teeth and achieved predictable long-term results. Longitudinal studies report an implant success rate of 96-99% in the mandible and 80-90% in the maxilla, for a period up to 15 years. Optimization of this success is directly related to the fabrication of passively fitting implant superstructures (Aguilar et al., 2010, Akalin et al., 2013).

The passive fit of an implant prosthesis is considered a significant factor in its long-term success (Assunção et al., 2010, Pjetursson et al., 2012). The contact of all fitting surfaces is thought to minimize the uncontrolled stresses and strains within the implant components, the prosthesis and surrounding bone in the absence of an applied external load (Abduo and Judge, 2014; Buzayan and Yunus, 2014). Furthermore, because of the precise fit of implant components and the rigid connection of the implant to the bone, small discrepancies can lead to stress applied to the implants when the framework is screwed (Del'Acqua, et al., 2010a).

Several investigators have described the effect of accurately fitted complete-arch fixed implant prosthesis on long-term success (Papaspyridakos et al., 2011).

Misfit increases the risk of biological and mechanical failures such as oclusal discrepancies screw or abutment loosening, fracture of the prosthetic components, implant fractures and loss of osteointegration (Kim et al., 2015).

Differently from natural teeth, osteointegrated implants have no periodontal ligament to compensate any inaccuracy of implant-retained prosthesis (Dhir et al.,2013). Although is difficult to obtain a completely passive fit, it is important to minimize the fit's discrepancy. Errors in the implant impression procedure during the fabrication of the final cast can cause misfit of the implant superstructure (Kim et al., 2015). Inaccurate frameworks of implant retained prosthesis can cause stress at the implant/ bone interface, plaque accumulation, affecting soft and/or hard tissues around the implants (Ericsson et al., 1995).

It is still unclear at which degree of prosthesis misfit will lead to biologic and/or mechanical complications (Papaspyridakos et al., 2014).

Nowadays we consider that the clinical fit of an implant prosthesis at the implant-abutment junction is directly dependent on the accuracy of impression technique (Papaspyridakos et al., 2014), and the fabrication of a precise definitive cast that exactly transfers its intraoral position for the long-term stability of the implant prosthesis (Kim et al., 2015).

The accuracy of implant impressions plays a significant role and serve as a starting point in the process of producing good working casts (Baig, 2014). Several factors influence the accuracy of a final cast for the fabrication of an implant prosthesis, such as, the impression technique used, the implant connection type, splinting or surface treatment of impression copings, the type of impression material used, the impression type, implant angulation and number, the depth of implant position, the dimensional stability of the gypsum used to fabricate the cast, the die system used and the length of the impression copings (Kim et al., 2015, Di Fiore et al., 2015, de Avila et al., 2014, Rutkunas et al., 2014, Buzayan et al., 2013, Lee et al., 2011, Hariharan et al., 2010).

1. Factors that may influence the accuracy of implant impressions

1.1. Impression technique (Open-tray vs. Closed-tray)

According to Del'Acqua (Del'Acqua et al., 2010a), an ideal impression technique would require minimal time and would be easy to perform, inexpensive, comfortable for the patient and, of course, give the best results.

Implant impressions techniques can be classified as either indirect (transfer) or direct (pick-up) and they are considered one of the major factors that can influence impression accuracy (Kim et al., 2015, Zen et al., 2014, Rutkunas et al., 2014).

The indirect (transfer) technique, also called closed tray impression technique, uses tapered copings and a closed tray to make an impression. The copings are connected to the implants, and an impression is made and separated from the mouth, leaving the copings intraorally. The copings are removed and connected to the implant

analogs, and then the coping analog assemblies are reinserted in the impression before fabricating the definitive cast (Ongul et al., 2012).

The direct (pick-up) technique uses square copings and an open tray, allowing the coronal end of the impression coping screw to be exposed. Before removing the tray, the copings are unscrewed so that they can be removed along with the impression. The implant analogs are connected to the copings to fabricate the definitive cast (Lee et al., 2008).

Twenty-five studies compared the differences between pickup and transfer impression techniques in terms of accuracy. Of the 25, 12 studies (Mostafa et al., 2010, Vigolo et al., 2004, Wostmann et al., 2008, Assunção et al., 2010, Lee et al., 2009, Del' Acqua et al., 2008, Barret et al., 1993, Phillips et al.,1994, Tarib et al., 2012, Kwon et al., 2011, Jo et al., 2010, Carr et al., 1991) concluded that pickup impressions were significantly more accurate than transfer, and 11 (Chang et al., 2012, Galluci et al., 2011, Wenz et al., 2008, Akça et al., 2004, Cabral et al., 2007, Herbst et al., 2000, Rashidan et al., 2012, Alikhasi et al., 2011, Walker et al., 2008, Conrad et al., 2007, Carr et al., 1999) showed no statistically significant differences between the two techniques. The evidence base supporting transfer over the pickup technique was negligible (Humphries et al., 1990, De La Cruz et al., 2002).

Comparing studies based on the relationship between the impression technique (pickup and transfer) and the number of implants, 11 studies (Galluci et al., 2011, Cabral et al., 2007, Lee et al., 2009, Tarib et al., 2012, Kwon et al., 2011, Jo et al., 2011, Carr et al., 1991, Alikhasi et al., 2011, Walker et al., 2008, Conrad et al., 2007, Carr et al., 1992) were identified as having used two or three implants. Among them, five studies (Lee et al., 2009, Tarib et al., 2012, Kwon et al., 2011, Jo et al., 2010, Carr et al., 1991) showed pickup was better than transfer, and a marginally higher number (Galluci et al., 2011, Cabral et al., 2007, Alikhasi et al., 2011, Walker et al., 2008, Conrad et al., 2007, Carr et al., 1992) elicited no differences between the two techniques. On the other hand, 12 studies (Chang et al., 2012, Mostafa et al., 2010, Stimmelmayr et al., 2012, Wenz et al., 2008, Wostmann et al., 2008, Akça et al., 2004, Assunção et al., 2010, Del' Acqua et al., 2008, Herbst et al., 2008, Barret et al., 1993, Phillips et al., 1994, De La Cruz et al., 2002) estimated accuracy with four to six implants; seven favoured pickup over transfer (Mostafa et al., 2010, Stimmelmayr et al., 2012, Wostmann et al., 2008, Assunção et al., 2010, Del' Acqua et al., 2008, Barret et al., 1993, Phillips et al., 1994)

and five showed no differences (Chang et al., 2012, Wenz et al., 2008, Akça et al., 2004, Herbst et al., 2008, De La Cruz et al., 2002).

A definite trend was observed, in that the pickup seemed to be better than transfer when there were higher numbers of implants involved (Baig et al., 2014).

1.2. Splinting vs. Nonsplinting

In order to ensure maximum accuracy for an implant-supported fixed dental prosthesis, it is recommended the intraoral splinting of transfer copings before taking the definitive impression, to preserve the tridimensional intraoral relationship and minimize the effects of distortion (Di Fiore et al., 2015, Rutkunas et al., 2014).

Most of the studies used polymethyl methacrylate (PMMA) autopolymerizing acrylic resin as the splinting material of choice and different techniques have been tested, such as dental floss, prefabricated acrylic resin bars and stainless steel burs (Naconecy et al., 2004; Papaspyridakos et al., 2012). Nevertheless, distortion can result from the residual polymerization contraction of the resin used for splinting. The use of new splinting materials such as composite resin or visible light polymerizing acrylic resin showed better results (Del'Acqua et al., 2010a, Papaspyridakos et al., 2012; Stimmelmayr et al., 2013).

Twenty-two in vitro and three clinical studies compared the accuracy of splinted *vs* nonsplinted impression techniques. Twelve in vitro studies reported that the splinted technique was more accurate than the nonsplinted technique (Al Quran et al., 2012; Assif et al., 1992; Assif et al., 1996; Del Acqua et al., 2012; Del'Acqua et al., 2010; Hariharan et al., 2010; Martinez-Rus et al., 2013; Naconecy et al., 2004; Ongul et al., 2012; Stimmelmayr et al., 2012; Vigolo et al., 2004; Vigolo et al., 2003), nine in vitro studies reported that there was no difference (Barrett et al., 1993; Chang et al., 2012; Del'Acqua et al., 2008; Herbst et al., 2000; Hsu, Millstein, and Stein, 1993; Humphries, Yaman and Bloem, 1990; Kim et al., 2006; Mostafa et al., 2010; Spector, Donovan and Nicholls, 1990) and one in vitro study (Phillips et al., 1994) reported that the nonsplinted technique was more accurate. The three clinical studies demonstrated that the splinted technique was more accurate than the nonsplinted technique and recommended this technique for clinical use (Papaspyridakos et al., 2012; Papaspyridakos et al., 2011; Stimmelmayr et al., 2013).

The splinted impression technique was more accurate than the nonsplinted conventional impression technique for completely edentulous patients (Papaspyridakos et al., 2014). Nevertheless, authors have identified potential problems with the splinted technique, such as fracture of the connection between the splint material and the impression copings, in particular due to shrinkage of splint material (Moreira et al., 2015).

Although there are conflicting data on the effects of different impression techniques and splinting, a systematic review as revealed that more studies reported higher accuracy with direct techniques when splinting was used (Rutkunas et al., 2014). Recent literature, pertaining to completely edentulous situations with four or more implants has demonstrated more accurate impressions with the splinted impression technique than with the nonsplinted type (Buzayan et al., 2013, Ongül et al., 2012, Lee et al., 2011, Filho et al., 2009, Assif et al., 1999).

1.2.1. Splinting Materials

The application of an autopolymerizing acrylic resin to a scaffold of dental floss still remains the most common technique to transfer copings. However, when a large volume of acrylic resin is used to splint the transfer copings intraorally, distortion may result from polymerization shrinkage, generating strains (Rutkunas et al., 2014, Del Acqua et al., 2010a). This is a time-consuming and technique-sensitive technique when multiple implants are to be restored in posterior region because unpolymerized resin can be displaced by the cheek or tongue, and the splint can be detached from the coping. It has been reported that the total shrinkage of acrylic resin is between 6.5% and 7.9% in the first 24 hours (Di Fiore et al., 2015). Another technique that has been suggested involves splinting the transfer copings with acrylic resin and perform an additional step of sectioning and re-joining the resin to reduce the effects of polymerization shrinkage and therefore the strains created. The chair-side time is increased with this technique (Di Fiore et al., 2015, Rutkunas et al., 2014).

Bite registration silicone and bite registration polyether as splinting materials were recently shown to have a positive influence on the accuracy of multi-unit implant impressions because of their rigidity and dimensional stability (Buzayan et al., 2013).

1.2.2. Polymerization Shrinkage

All resin-based materials present polymerization shrinkage. The polymerization shrinkage of pattern resins contributes to distortion in implant prosthesis fabrication, this is a concern, because the production of high-quality restorations demands accuracy (Gibbs et al., 2014).

Regarding the use of photopolymerizing acrylic resins, studies refer no relevant differences in polymerization shrinkage between the ones presented in gel form compared to autopolymerizing acrylic resin. However, when comparing photopolymerizing resins presented in paste form, they show a higher polymerization shrinkage value when compared with both the ones in gel form and the autopolymerizing resins (Gibbs et al., 2014).

1.3. Impression Materials

Some impression materials properties, such as rigidity and dimensional stability, can influence the accuracy of the implant impression, the accuracy of the solid implant cast, and ultimately, the accuracy of the cast implant framework. When the direct implant impression technique is used, the impression material must: 1) be rigid enough to hold the direct impression coping and to prevent accidental displacement of the coping when an abutment is connected, and 2) have minimal positional distortion between the abutment replicas when compared with its intraoral implant abutments (Wee, 2000).

Rigid elastomeric impression materials, such as polyether (PE), would secure the impression copings accurately, and it has dimensional stability, high resistance to permanent deformation, and high primary shear resistance with little creep under compressive forces, making it an optimal material for making impressions of implants.

Polyvinyl siloxane (PVS) impression materials have been widely accepted because of their excellent dimensional stability, superior recovery from deformation, and precise reproduction of details (Del'Acqua, Chavez, Amaral, et al., 2010).

Recently, advances made both in chemical and physical properties of these materials, have made PE and PVS the materials of choice for implant impression. To date, many researchers have evaluated implant impression accuracy and found better

results with PE and PVS versus condensation silicone, polysulfide, irreversible hydrocolloid, and plaster materials (Akalin et al., 2013; Lee, So, et al., 2008).

Regarding to the type of impression material used, PVS and PE were the preferred impression materials for multi-unit implant impressions referred in the literature. The majority of the have shown comparable accuracy, with insignificant differences between PVS and PE for multi-implant impressions, but a few others have reported greater accuracy with PVS in comparison to PE (Baig et al., 2014, Buzayan et al., 2013, Yamamoto et al., 2010).

Among the analyzed papers, the majority of the studies reported no difference between PE and PVS (Aguilar et al., 2010; Akalin et al., 2013; Assif, Nissan, Varsano, & Singer, 1999; Barrett et al., 1993; Chang et al., 2012; Ferreira et al., 2012; Mostafa et al., 2010; Ortorp, Jemt, & Back, 2005; Spector et al., 1990; Wee, 2000; Wenz & Hertrampf, 2008) while one study reported better accuracy with PE (Del'Acqua, Chavez, Amaral, et al., 2010).

A systematic review concluded that the accuracy of implant impressions is not affected by the impression material (PE and PVS) for completely edentulous patients (Papaspyridakos et al., 2014).

1.4. Implant angulation e number

Relating to the placement of the implants, parallel or nonparallel, most of the studies described in the literature refer that implant angulation of 20 to 25 degrees negatively affected the multi-unit implant impression accuracy (Baig et al., 2014). According to Assunção et al (2010), when the impression is totally covered by plaster, perpendicular analogs are exposed to minor vertical forces as compared to leaning analogs, which results in lesser displacement of less leaning analogs (Assunção et al., 2010).

1.5. Implant connection type (Internal vs. External)

One of the features that has been the object of debate among the systems is the design of the connection that allows the prosthetic suprastructure to be attached to the implants. Two types of connections are available: external and internal connection.

While the external connection (EC) usually has an external hexagon on the implant platform, the internal connection (IC) can be divided into internal hexagon, internal octagon and Morse taper connection (Goiato et al., 2015).

Historically, the Bränemark system was characterized by an external hexagon, which was developed to facilitate implant insertion and provide an antirotational mechanism. However, this configuration has some drawbacks due to the existence of a microgap in the implant-abutment interface and to its limited height. For this reason, it has been hypothesized that, under high occlusal loads, the external hexagon might allow micromovements of the abutment, consequently causing instability of the implant/abutment connection, which may result in abutment screw loosening or even fracture. IC implants were therefore introduced to increase the implant-abutment contact area, providing greater stability and bacterial seal (Goiato et al., 2015; Gracis et al., 2012)**.**

Despite the lack of *in vivo* or *in vitro* studies that directly compare the influence of internal and external implant connections for abutments/reconstructions on the accuracy of implant-level impressions, a recent study suggested that that internal connection implants present better results on the accuracy of implant impressions comparing to external connection implants (Ventura et al., 2016).

1.6. Other factors - Impression type (Conventional vs. Digital); Connection level – implant level/abutment level; Impression tray type – stock/custom tray; Depth of implant placement

Research on digital implant impressions for completely edentulous jaws is limited to a few in vitro studies (Abdel-Azim, Zandinejad, Elathamna, Lin, & Morton, 2014; Papaspyridakos et al., 2015). Papaspyridakos et al., 2015 concluded that digital implant impressions are as accurate as conventional implant impressions. Abdel-Azim et al., 2014 reported that, for complete-arch frameworks, the digital impression resulted in an overall more accurate fit when compared to the conventional closed-tray impression.

Other studies examined the effects of various factors on the accuracy of implant impressions, such as different connection levels (implant level and abutment level) (Alikhasi, Siadat, Monzavi, & Momen-Heravi, 2011; Bartlett, Greenwood, & Howe,

2002; Daoudi, Setchell, & Searson, 2001), different impression trays (Burns, Palmer, Howe, & Wilson, 2003; Simeone, Valentini, Pizzoferrato, & Scudieri, 2011) and implant depth (Lee, Ercoli, Funkenbusch, & Feng, 2008).

Too few studies were available to draw any conclusions. Further studies, including clinical trials, are required to provide more evidence about clinical factors that affect the implant impression accuracy.

The purpose of the present study is to evaluate if there is any significant difference in accuracy of implant impressions using two different splinting materials: **Group A** - photopolymerizing composite (Conlight; Kuss Dental, Madrid, Spain) and **Group B** - PMMA autopolymerizing acrylic resin (GC pattern™; GC Corp, Tokyo, Japan). The following null hypothesis was tested in this study: (1) There are no differences in implant-level impressions accuracy between the ones splinted with Conlight and the ones splinted with GC.

II. Materials and Methods

1. Type of study

In vitro study.

2. Study design

This study compared the influence of two different splinting materials on implant impressions accuracy: **Group A** (photopolymerizing composite - Conlight; Kuss Dental, Madrid, Spain) and **Group B** (PMMA autopolymerizing acrylic resin - GC pattern™; GC Corp, Tokyo, Japan). For each group, 10 sample impressions were made from a standardized master cast. After pouring, measurements were made in each working cast and the differences between them were analyzed.

3. Reference bar construction

A dental stone cast was fabricated by duplicating an edentulous mandibular arch. Four slightly oversized holes were made bilaterally in the intra-mental foramen region

to insert four external connection implant analogs (Biomet 3i®, Florida, USA) with 4.10 mm in diameter and 10 mm in length. The implant analogs were placed simulating a supra osseous clinical environment, parallel to each other and fixed using wax to make their removal possible after fabrication of the framework.

Corresponding burnout cylinders were placed on the implant analogs and splinted with wax (**Figure 1**) in order to fabricate a cobalt-chromium alloy framework.

4. Master cast construction

Implant analogs were attached to the reference framework and then inserted into the holes on the stone cast, in order to guarantee a complete passive fit. A matrix for pouring the definitive master cast was made using condensation silicone (Zetalabor; Zhermack®, Badia Polesina, Italy) over the stone cast with the reference bar attached.

The master model (**Figure 2**) was fabricated with polyurethane (Sherapolan 2:1; Shera®, Lemförde, Germany) and the four implant analogs were numbered anti-clockwise from 1 to 4 based on a frontal view of the master cast.

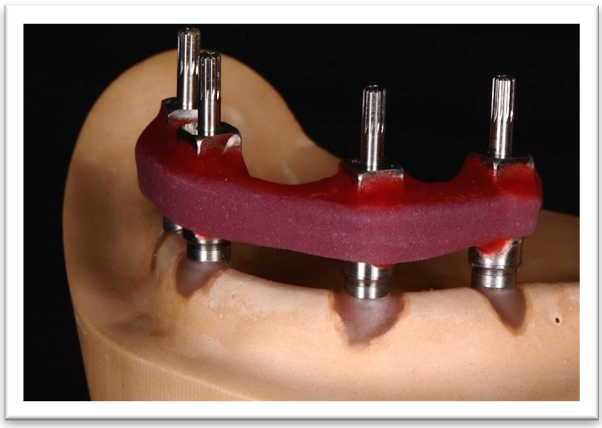

***Figure 1* – analogs splinted with wax.**

***Figure 2* – master model with reference bar.**

5. Impression Procedure

Acrylic stock trays were used for all impressions in the splinted open-tray technique. Four openings were drilled to allow access for the coping screws and a thin layer of vinyl polysiloxane adhesive (**Figure 3**) (Panasil® Adhesive, Kettenbach®, Eschenburg, Germany) was applied to ensure adequate adhesion between the impression tray and the impression material.

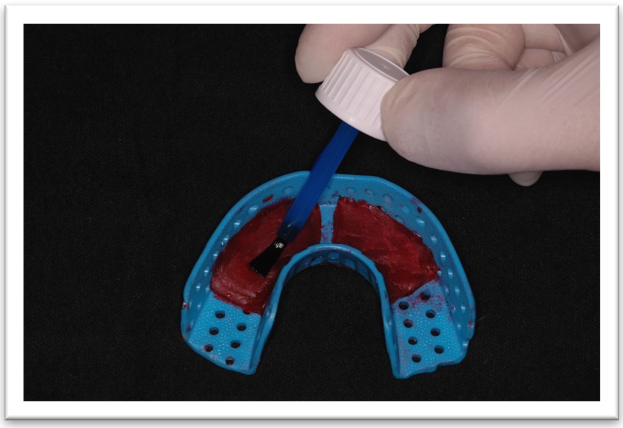

***Figure 3* – tray with vinyl polysiloxane adhesive.**

The implant copings were splinted with a matrix of dental floss (**Figure 4**) (ACCLEAN®, Henry Schein®, New York, USA). In Group A, the impression copings were splinted with photopolymerizing composite (**Figure 5**) (Conlight; Kuss Dental, Madrid, Spain) In Group B, the impression copings were then splinted with autopolymerizing acrylic resin (**Figure 6**) (GC pattern™; GC Corp, Tokyo, Japan).

***Figure 4* – matrix of dental floss.**

***Figure 5* – implant analogs splinted with Conlight.**

***Figure 6* – implant analogs splinted with GC.**

A total of twenty impressions were obtained - ten for each group - in accordance with manufacturer's directions using a two-step impression technique: Putty - consistency vinyl polysiloxane (Panasil® Putty Soft, Kettenbach®, Eschenburg, Germany) (**Figure 7**) was used as a tray material combinated with light-consistency vinyl polysiloxane (Panasil® Initial Contact Light, Kettenbach®, Eschenburg, Germany) (**Figure 8**) meticulously injected around the impression copings to ensure complete coverage.

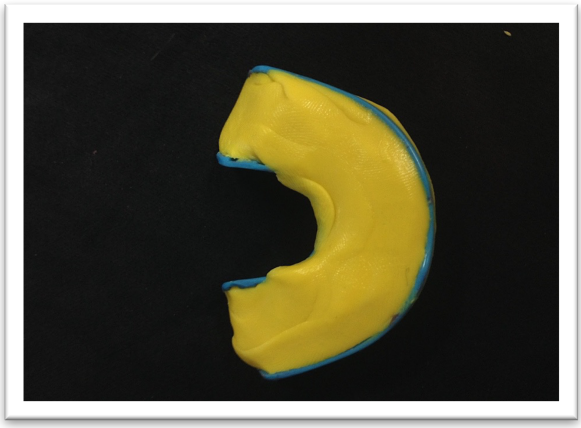

***Figure 7* – Panasil® Putty Soft applied in the tray.**

***Figure 8* – Panasil® Initial Contact Light injected around the impression copings.**

The tray was seated on master cast with hand pressure throughout the setting time - 4 minutes. (**Figure 9**) The guide pins were unscrewed so that the transfer copings remained in the impression when the tray was removed.

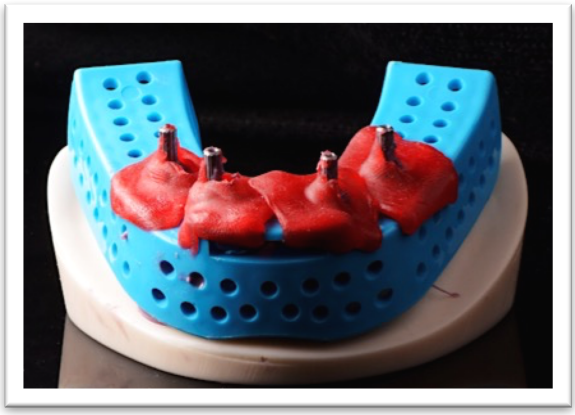

***Figure 9* – Impressure procedure – open tray technique.**

For all impressions, implant transfer copings (Biomet 3i®, Florida, USA) for the open tray technique were used.

6. Cast production protocol

Standardized laboratory procedures were performed after at least 30 minutes. First, matching implant analogs were attached manually to the transfer copings.

Then, the impressions were poured with type IV dental stone (GC Fujirock EP®; GC Corp, Tokyo, Japan) and vacuum-mixed following manufacturer recommendations. (**Figure 10 and 11**) A single operator performed all laboratory procedures. All casts were stored at room temperature for a minimum of 24 hours before measurements were made.

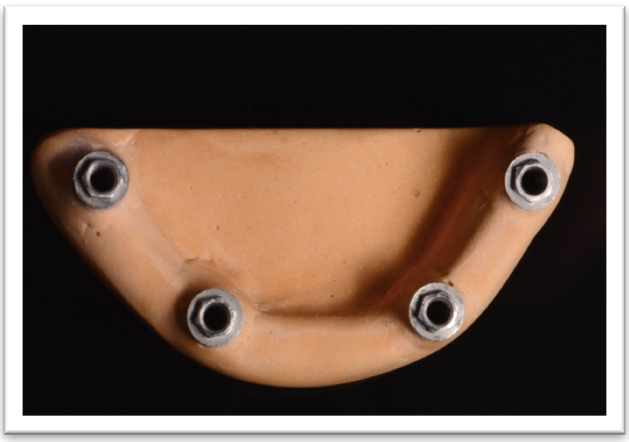

Figure 10 **– dental stone cast – upper view.**

Figure 11 **– dental stone cast – frontal view.**

7. Measurement protocol

Each cast produced was assessed for accuracy by attaching the reference framework with a single screw on analog number 1 (**Figure 12**) and measuring the vertical fit discrepancy using a toolmakers' microscope (**Figure 13)** (Toolmaker's Microscope, Mitutoyo).

The accuracy of bar fit was quantified by measuring the vertical gap between each cylinder and the respective analog (2, 3 or 4) at four different points - buccal, lingual, distal and mesial. Demarcations were made in the center of each side of the

framework's cylinders to standardize the area for image capture. All measurements were done by the same operator.

Figure 12 **– Reference bar with a single screw on analog 1.**

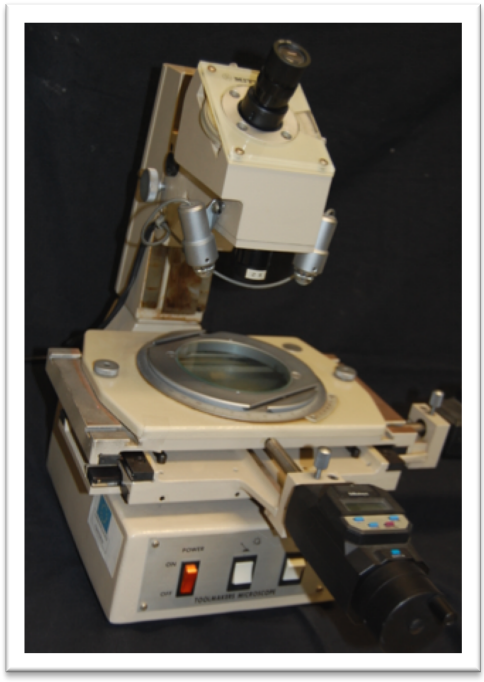

Figure 13 **– Toolmaker's microscope.**

8. Statistical analysis

The statistical analysis of the results was performed at three levels:

1) In Group A, a comparison of all buccal, lingual, mesial and distal measures was made separately;

2) In Group B, a comparison of all buccal, lingual, mesial and distal measures was made separately;

3) A comparison between Group A and B was performed by evaluating each implant (2, 3 or 4) / point (buccal, lingual, distal or mesial) combination.

Kolmogorov-Smirnov and **Shapiro-Wilk Tests** were used to access whether the data followed a normal distribution; the **Levene's Test** was computed to determine if the assumption of equal variances was valid.

Kruskall-Wallis and **Mann-Whitney Tests** (Nonparametric Tests) were performed accordingly to the size of the sample, when the conditions referred were not observed (normal distribution and equal variances).

T-student Test (Parametric Test) was performed when the conditions referred were observed (normal distribution and equal variances).

The level for statistical significance was set at 5% ($p<0.05$) for all tests that were performed.

III. Results

The results of the study in terms of measurements obtained through the microscope analysis are summarized in **Appendix F.** In each model, the vertical gap was measured on implant analog number 2, 3 and 4; for each implant analog the measurements were made at four different points – buccal, lingual, distal and mesial.

1. Group A – Photopolymerizing

In Group A, in order to compare all buccal, lingual, mesial and distal values separately between implant analogs, a nonparametric test was applied due to the small size of the samples, and because after performing **Shapiro-Wilk Test** it was verified for all categories that the measurements on the 3 samples (implant analog 2, 3 and 4) did not follow a normal distribution.

Since the intention is to compare more than 2 samples, the nonparametric test **Kruskall-Wallis** was performed. The results show there are no significant differences between implant analogs concerning distances at buccal, lingual, mesial and distal points, since the p-value>0,05 (**Table 1**)

Table 1

Statistical Comparison of Each Point between Implant Analogs – Group A

	Data follow normal distribution	**Significant differences between implant analogs**
Buccal points	**No** (2*p*-values<0,05)	**No** (*p*-value>0,05)
Lingual points	**No** (1*p*-value<0,05)	**No** (*p*-value>0,05)
Mesial points	**No** (2*p*-values<0,05)	**No** (*p*-value>0,05)
Distal points	**No** (1*p*-value<0,05)	**No** (*p*-value>0,05)

2. Group B – Autopolymerizing

In Group B, in order to compare all buccal, lingual, mesial and distal values separately between implant analogs, a nonparametric test was applied due to the small size of the samples, and because after performing **Shapiro-Wilk Test** it was verified that all but one (buccal points) did not follow a normal distribution. However, **Levene's Test** determined that the assumption of equal variances was not valid for this category.

Since the intention is to compare more than 2 samples, the nonparametric test **Kruskall-Wallis** was performed. The results show there are significant differences between implant analogs concerning distances at buccal and mesial points, since the p-value<0,05 (**Table 2**).

Table 2

Statistical Comparison of Each Point between Implant Analogs – Group B

	Data follow normal distribution	**Significant differences between implant analogs**
Buccal points	**Yes** (*p*-values>0,05)	**Yes** (*p*-value<0,05)
Lingual points	**No** (1*p*-value<0,05)	**No** (*p*-value>0,05)
Mesial points	**No** (1*p*-value<0,05)	**Yes** (*p*-value<0,05)
Distal points	**No** (1*p*-value<0,05)	**Yes** (*p*-value<0,05)

With respect to buccal and mesial points, statistically significant differences were observed between implant analogs 2 and 3 and between implant analogs 2 and 4. It was verified that the vertical gap on implant analog 2 is significantly lower than the ones on implant analogs 3 and 4.

3. Comparison between Groups

The comparison between Group A and B was performed by analyzing each implant analog/ point combination.

After performing **Shapiro-Wilk Test**, it was verified that the measurements at each combination did not follow normal distribution.

Data was analyzed performing **Mann-Whitney Tests** (nonparametric tests), since the values did not come from normal populations.

The results showed there were significant differences between photopolymerizing and autopolymerizing groups, concerning measurements in all implant/point combinations (**Table 3**).

Larger gaps were found when the measurements in the stone casts were obtained from autopolymerizing group.

It was concluded that Group B (autopolymerizing) presented vertical gaps statistically higher than the ones verified in Group A (photopolymerizing).

Table 3

Statistical Comparison of Each Combination between Group A and B

	Data follow normal distribution	**Significant differences between implant analogs**
Implant 2, Buccal point	**No** (p-values<0,05)	**Yes** (p-value<0,05)
Implant 2, Lingual point	**No** (p-values<0,05)	**Yes** (p-value<0,05)
Implant 2, Mesial point	**No** (p-values<0,05)	**Yes** (p-value<0,05)
Implant 2, Distal point	**No** (p-values<0,05)	**Yes** (p-value<0,05)
Implant 3, Buccal point	**No** (p-values<0,05)	**Yes** (p-value<0,05)

(to be continued)

(continuation)

Implant 3, Lingual point	**No** (*p*-values<0,05)	**Yes** (*p*-value<0,05)
Implant 3, Mesial point	**No** (*p*-values<0,05)	**Yes** (*p*-value<0,05)
Implant 3, Distal point	**No** (*p*-values<0,05)	**Yes** (*p*-value<0,05)
Implant 4, Buccal point	**No** (*p*-values<0,05)	**Yes** (*p*-value<0,05)
Implant 4, Lingual point	**No** (*p*-values<0,05)	**Yes** (*p*-value<0,05)
Implant 4, Mesial point	**No** (*p*-values<0,05)	**Yes** (*p*-value<0,05)
Implant 4, Distal point	**No** (*p*-values<0,05)	**Yes** (*p*-value<0,05)

Table 4

Descriptive Statistics of the Vertical Gap in mm for the Two Groups Tested – Buccal

	Count	**Mean**	**Min**	**Max**
Photopolymerizing	30	0.0115	0.0011	0.0560
Autopolymerizing	30	0.0375	0.0120	0.1010

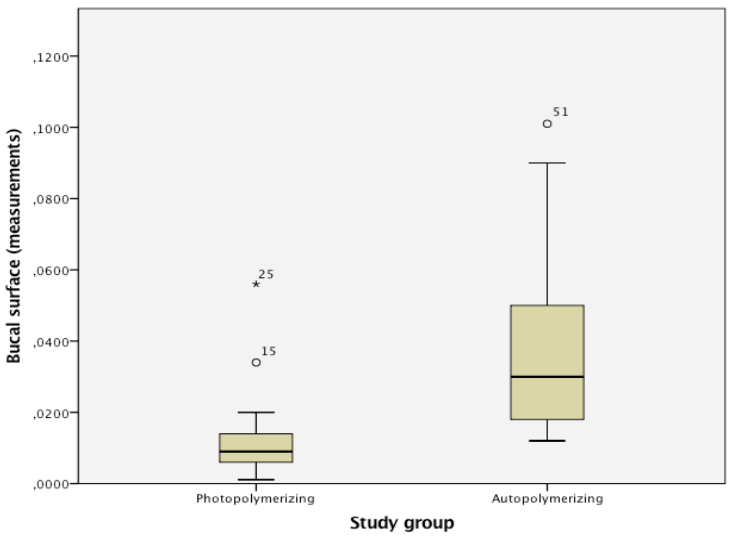

***Figure 14* - Box-whisker plots of the vertical gap in mm for the two groups tested – buccal points.**

Table 5

Descriptive Statistics of the Vertical Gap in mm for the Two Groups Tested – Lingual

	Count	**Mean**	**Min**	**Max**
Photopolymerizing	30	0.0102	0.0030	0.0690
Autopolymerizing	30	0.0355	0.0120	0.1200

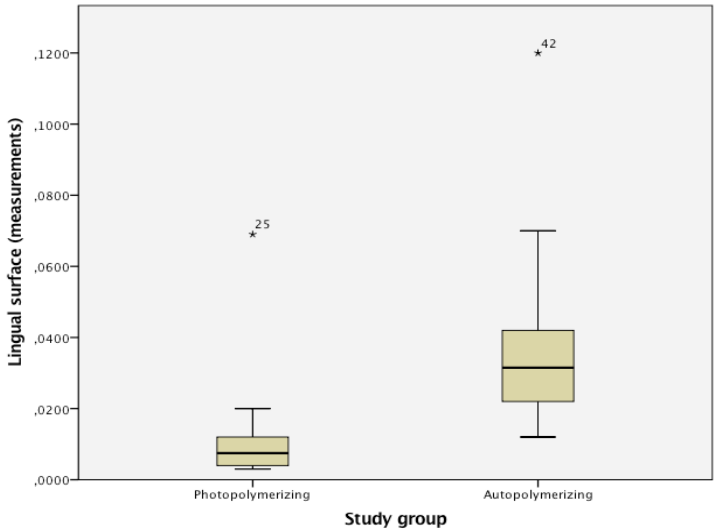

***Figure 15* - Box-whisker plots of the vertical gap in mm for the two groups tested – lingual points.**

Table 6

Descriptive Statistics of the Vertical Gap in mm for the Two Groups Tested – Mesial

	Count	**Mean**	**Min**	**Max**
Photopolymerizing	30	0.0100	0.0030	0.0610
Autopolymerizing	30	0.0379	0.0110	0.1190

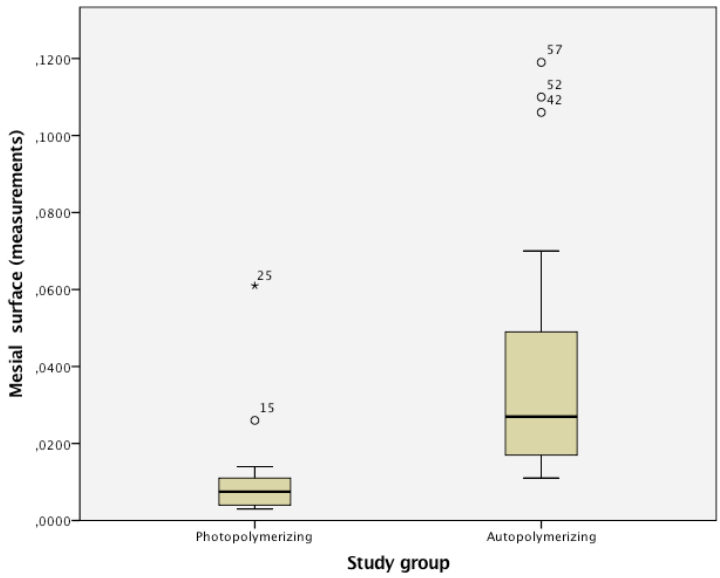

Figure 16 **- Box-whisker plots of the vertical gap in mm for the two groups tested – mesial points.**

Table 7

Descriptive Statistics of the Vertical Gap in mm for the Two Groups Tested – Distal

	Count	Mean	Min	Max
Photopolymerizing	30	0.0125	0.0010	0.0890
Autopolymerizing	30	0.0457	0.0150	0.1580

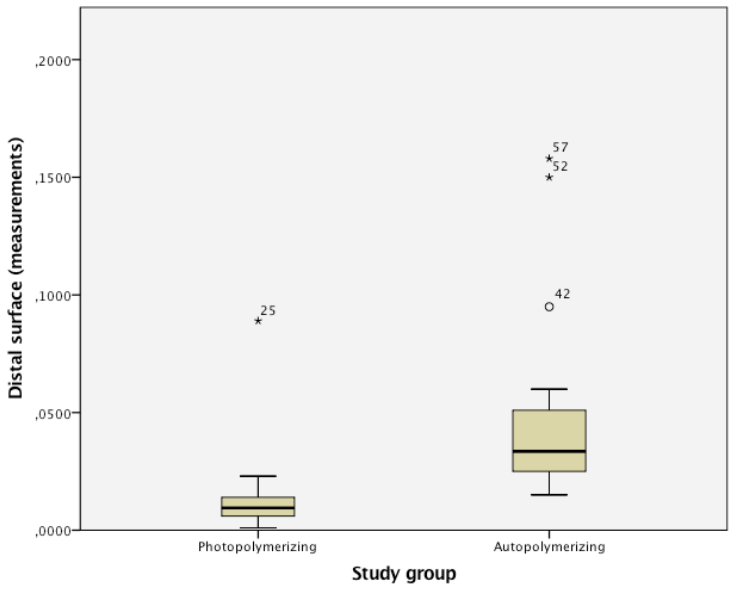

Figure 17 **- Box-whisker plots of the vertical gap in mm for the two groups tested – distal points.**

IV. Discussion

The results of this study suggest that implants splinted with photopolymerizing composite (Conlight; Kuss Dental, Madrid, Spain) - **(Group A)** yielded significantly more accurate impressions than implants splinted with PMMA autopolymerizing acrylic resin (GC pattern™; GC Corp, Tokyo, Japan) - **(Group B)**.

The null hypothesis that there would be no significant differences on the accuracy of implant impressions regardless of the splinting material used was rejected. Since there are no previously published *in vivo* or *in vitro* studies comparing the same splinting materials, the conclusion of this investigation cannot be compared.

Working casts should accurately represent the clinical relationship of the implants allowing the fabrication of passively-fitting prostheses. Consequently, there will be an elimination of strain on the supporting implant components and the surrounding bone (Del'Acqua et al., 2008). The effect of different factors on the accuracy of implant impressions has been mainly investigated *in vitro* resulting in limited clinical data.

Although passive fit is supposed to be one of the most vital requirements for the maintenance of the osseointegration, and the fact that literature presents considerable information regarding the framework's misfit, there is no consistency on a specified number or even a range of clinical misfit to be accepted (Buzayan and Yunus., 2014).

This study presented large differences in the mean values and standard deviations. In most measurements, the connections showed good mean results, but with great variations. This fact suggests that the same connection does not behave homogenously. Results can be influenced by the micrometric tolerance inherent in the machining of the prosthodontic components and by the measurement method employed. Just one screw was tightened to the framework, leading to amplification of the gap values (Del'Acqua et al., 2010a).

The results obtained are in conformity with the data from the reports by Jemt, 1991 and Tan et al., 1993. The authors suggested that the one-screw test for evaluation of framework fit showed that vertical discrepancies tend to be magnified at the opposite terminal abutment. The only exceptions are the lingual and mesial points in the autopolymerizing group, which showed higher measurements on implant analog

number 3 than on number 4. However, these discrepancies are often masked if the distortion occurred in the negative z-axis direction (Fernandez et al., 2013).

Kalus and Bessing, in 1994, developed a rating scale for evaluating the fit of a framework. In the referenced study, the prosthesis was seated on abutments and tightened with one screw in the abutment number 1. The vertical gap between the cylinder and the abutment number 4 was given a rating using a 4-point scale: 0=no visible discrepancy, 1=slight discrepancy indicating a clear elevation of the framework with a gap less than 0.5 mm, 2= a moderate discrepancy of approximately 0.5 to 1 mm, and 3=pronounced discrepancy with a gap of clearly more than 1 mm. If this classification had been used in the present study, all the results would have been 0 or 1, since the largest gap value measured for an analog was 0.158 mm (158 μm). In cases where the fit was 0, a gap between the abutment and framework would have been detectable only microscopically (Del'Acqua et al., 2010a).

Nowadays, despite still being unclear the amount of prosthesis misfit that will lead to biologic and/or mechanical complications (Papaspyridakos et al., 2014), the significance of passive clinical fit of an implant-supported prosthesis has been highlighted in the literature to prevent complications (Papaspyridakos et al., 2011).

Experienced operators cannot detect clinically discrepancies of less than 30 μm in the fit of an implant-retained framework on multiple abutments. This figure could serve as a criterion between acceptable and unacceptable frameworks (Herbst et al., 2000). Jemt, 1991 and May et al., 1997 suggested that discrepancies on the order of 100 to 150μm fall within a clinical range of passive fit. As follows, based on the results achieved in this study, both of the splinting materials examined produce clinically acceptable results, if evidence-based protocols are followed. The lack of any reference value for defining misfit makes it difficult to recommend any particular type of material.

The results of this study draw attention to the fact that even with standardized *in vitro* conditions the exact spatial reproduction of the implant positions in a working cast is impossible to achieve. Therefore, the ideal objective is difficult to fully realize clinically because of the potential for distortion of the stone cast, which is caused by a combination of dimensional errors in the transfer process of the replicas, and also because framework adaptation may change when the retaining screws are tightened (Herbst et al., 2000).

Implant components displacements can be introduced during the process of producing a definitive cast. The first is the displacement of each impression coping on the mating surface of each implant. The difference in rest position between the components when they are screwed is defined as machining tolerance (Fernandez et al., 2013).

Machining tolerance differs among different implant systems, representing an unknown variable in accuracy measurements (Ma et al., 1997). Herbst et al., 2000 showed that connecting an impression coping or an abutment replica could introduce more than 30 μm of displacement. Therefore, when the results of the studies investigating implant impression accuracy are interpreted, the machining tolerance should be considered as one of the factors affecting accuracy (Martinez-Rus et al., 2013).

The second factor is the displacement of each impression coping from the impression technique. Unscrewing the guide pins from the impression copings when the tray is removed from the mouth/model or screwing the matching abutment replicas in the impression may lead to minor movement and thus influence cast accuracy (Vigolo et al., 2003).

Paired prosthetic components may be rotationally displaced during connection to their respective parts. This displacement cannot be controlled by the clinician and lies within the range of the inherent machining tolerance. Hence, errors occur during the connection of impression copings to the implants intraorally and to the implant analogs in the laboratory, respectively (Papaspyridakos et al., 2012).

The materials and methods of the present study were standardized to allow a careful evaluation of different types of splinting materials, while isolating other related variables, particularly those associated with laboratory procedures such as setting time and use of direct technique.

Some authors reported that implant angulation causes distortion of the impression material on removal. Therefore, the greater the divergence between analogs, the more imprecise the impression will be (Del'Acqua et al., 2008). To refer that the implant analogs in the master casts of this study were parallel to each other and perpendicular to the surface, which minimized this factor.

A possible limitation of this study is the use of manual torque to tighten the reference framework to the work casts. A torque driver should be used in order to apply

an even force of 10Ncm. When a higher torque is used, there is a risk of screw fracture, the vertical discrepancy may have been reduced, and there inevitably would have been transfer of stresses to the implant analogs and screws (Del Acqua et al., 2010a). Nevertheless, dentists in their day-to-day clinical practice usually apply the method used in this study.

None of the prosthesis fabrication methods employed in this study have been able to produce frameworks with absolute passive fit (Papaspyridakos et al., 2011). A perfect fit occurs when all the matching surfaces of the implant and framework are aligned and in contact without the application of force (Del Acqua et al., 2010a). In this study, the lost-wax technique was used to fabricate the reference bar used throughout the measurements. It is known that the accuracy of this technique depends on multiple factors, including waxing technique and alloy behavior (Fernandez et al., 2013). In order to control these error sources, the position of the implant analogs in the master cast was determined only after casting the reference framework, attaching the analogs to the respective bar before pouring the definitive models.

The fact that implant analogs were placed in the same position in both groups using the transference bar, minimized the differences between them and standardized the conditions.

Many in vitro studies used block shape master models with flat impression surfaces included. Nonetheless, neither of these can simulate the deformation that takes place in impression material upon removal, since curved-arch models were not used (Akalin et al., 2013). In the current study, a master model with an anatomic shape resembling the edentulous mandible was used.

The use of polyether or polyvinyl siloxane for direct multi-implant impressions for edentulous arches, produces similarly accurate implant casts (Chang et al., 2012), accordingly to the literature.

All impressions were made in a controlled-temperature environment ($23^{o}C\pm 2^{o}C$) and no control of the humidity. The manufacturer's setting time was doubled in order to compensate for a delayed polymerization reaction at room temperature rather than at mouth temperature (Del Acqua et al., 2010b).

The number of articles that have evaluated the influence of tray type on the accuracy of implant impressions is very limited. Burns et al., 2003, showed that custom trays produce more precise impressions than stock trays. Nevertheless, because of the additional time and cost required to fabricate custom trays, dentists tend to use stock

trays that show favorable results, when correctly chosen (Del'acqua et al., 2012).

The pouring procedure can alter the analogs' relationship because of the plaster expansion (Del'Acqua et al., 2010a). IV dental stone was employed because of its linear setting expansion of 0,10% at most (Fernandez et al., 2013, Herbst et al., 2000) and vacuum-mixed following manufacturer recommendations.

In the present study, a toolmakers' microscope (Toolmakers Microscope, Mitutoyo) was used to measure the gap width between the metal framework and the analogs of the respective working cast at selected points. However, due to the fact that inaccuracy is expressed in only one dimension, information may be lost (Martinez-Rus et al., 2013). The inaccuracies seen in these vertical measurements may be enough to demonstrate the complexity of achieving "passive fit". More research in this area should be performed to evaluate eventual tridimensional movements of implant analogs in the working casts.

Some authors suggest that splinting the transfer copings with a splinting material and perform an additional step of sectioning and re-joining the material reduces the effects of polymerization shrinkage and therefore the strains created. The chair-side time is increased with this technique (Di Fiore et al., 2015, Rutkunas et al., 2014). This technique was not used in the present study because we wanted to compare and evaluate how polymerization shrinkage of the two splinting materials used in the present study would influence the implant impression accuracy.

Further studies are required to fully understand the influence of splinting material type (photopolymerizing or autopolymerizing) on the accuracy of implant impressions. To corroborate the findings of the present study, larger samples and more implant systems should be evaluated. Moreover, knowledge of the machining tolerances for the specific implant systems could be necessary before making fit measurements (Braian et al., 2014).

Despite this study indicates that using a photopolymerizing composite (Conlight; Kuss Dental, Madrid, Spain) as splinting materials produce significantly more accurate impressions comparing with using an autopolymerizing resin (GC pattern™; GC Corp, Tokyo, Japan), additional in vivo studies would be helpful to establish the clinical relevance of this finding. It is also necessary to define the threshold, that distinguishes misfit from acceptable fit (Braian et al., 2014). This information could be useful for clinicians to understand and respect the level of precision that is needed for implant-supported prostheses on the implant level.

V. Conclusion

Within the limitations of the present laboratory study, the results suggest that the photopolymerizing splinted composite (Conlight; Kuss Dental, Madrid, Spain) presents better results on the accuracy of implant impressions comparing to PMMA autopolymerizing acrylic splinted resin (GC pattern™; GC Corp, Tokyo, Japan). Implant-level impressions made with PMMA autopolymerizing splinted resin resulted in statistically lower accuracy than the ones made in the photopolymerizing composite group.

Clinical significance: Improved accuracy of implant impressions may be obtained if a photopolymerizing composite (Conlight; Kuss Dental, Madrid, Spain) is used instead of a PMMA autopolymerizing resin (GC pattern™; GC Corp, Tokyo, Japan) as splinting materials.

VI. Appendices

APPENDIX A

Implant components, References and Batch Numbers

Table 8

Materials, Manufacturers, Components and Batch Numbers

Manufacturer: Biomet 3i®, Florida, USA **Description**	**Reference**	**Batch number**
External connection Implant Analog (master cast)	ILA 20 4.1mm	1174319
External connection Implant Analog (master cast)	ILA 20 4.1mm	1177288
External connection Implant Analog (master cast)	ILA 20 4.1mm	1177288
External connection Implant Analog (master cast)	ILA 20 4.1mm	1174098
External connection Multiunit (transference bar)	LPC441U 1mm	2012110288
External connection Multiunit (transference bar)	LPC441U 1mm	2013101326
External connection Multiunit (transference bar)	LPC441U 1mm	2013092050
External connection Multiunit (transference bar)	LPC441U 1mm	2014090941
Multiunit impression coping (transference bar)	LPCPIC2	2014102238
Multiunit impression coping (transference bar)	LPCPIC2	2014102238
Multiunit impression coping (transference bar)	LPCPIC2	2014102238
Multiunit impression coping (transference bar)	LPCPIC2	2014102238
External connection impression coping (impressions)	IIC12	1162761
External connection impression coping (impressions)	IIC12	1162761
External connection impression coping (impressions)	IIC12	1118757
External connection impression coping (impressions)	IIC12	1162761
External connection Implant Analog (study cast)	ILA20	1180076
External connection Implant Analog (study cast)	ILA20	1177296
External connection Implant Analog (study cast)	ILA20	1177288
External connection Implant Analog (study cast)	ILA20	1177288
External connection Implant Analog (study cast)	ILA20	1180323
External connection Implant Analog (study cast)	ILA20	1180323
External connection Implant Analog (study cast)	ILA20	1180323

(to be continued)

(continuation)

Manufacturer: Biomet 3i®, Florida, USA **Description**	**Reference**	**Batch number**
External connection Implant Analog (study cast)	ILA20	1180323
External connection Implant Analog (study cast)	ILA20	1180323
External connection Implant Analog (study cast)	ILA20	1180323
External connection Implant Analog (study cast)	ILA20	1180076
External connection Implant Analog (study cast)	ILA20	1180076
External connection Implant Analog (study cast)	ILA20	1178095
External connection Implant Analog (study cast)	ILA20	1178095
External connection Implant Analog (study cast)	ILA20	1178095
External connection Implant Analog (study cast)	ILA20	1178095
External connection Implant Analog (study cast)	ILA20	1178095
External connection Implant Analog (study cast)	ILA20	1178095
External connection Implant Analog (study cast)	ILA20	1178095
External connection Implant Analog (study cast)	ILA20	1178095

APPENDIX B

Conlight®; Kuss Dental® – Instructions for use

Conlight

Instructions for use	English

Product description

Conlight is a light-curing gel modelling resin developed for building up indirect post and cores using the direct technique (intraorally). It can be applied directly from the dispensing syringe, invested after trimming and replaced in metal or porcelain. **Conlight** is easily cured with a standard light-curing unit (320 – 500 nm, e.g. a hand-held light). It is cured without vacuum. **Conlight** is not suitable for permanent fitting intraorally. It can be applied directly from the dispensing syringe and burns out without residue.

Composition

Composition of acrylic resin, fillers and initatiors.

Areas of application

- Build-up of indirect post and cores using the direct technique
- Intraoral splinting of cast frameworks for soldering
- Intraoral fixation of secondary and tertiary units
- Fabricating bite stopps

Properties and advantages

Though flowable when applied, **Conlight** is immediately positionally stable. The material can be inserted into the prepared access cavity without a matrix and the post and core can be modelled to the correct contour. Due to the material properties of **Conlight** a minimum amount of material and time is required. **Conlight** is tasteless and odour-free. It can be trimmed after it has been polymerised with a standard light-curing unit. The trimmed post and core is very stable and accurate and can be removed without distortion. **Conlight** burns out without residue and guarantees an excellent fit of the cast root post.

Instructions for use

After removing the cap, attach one of the application tips supplied for precise application. The tips are intended for single use. The dispensing syringe should be sealed again after use. To ensure shrinkage is kept to a minimum during curing, **Conlight** should be applied and polymerised in a maximum layer thickness of 2 mm. Polymerising layers thicker than 2 mm can result in excessive heat release and stresses. This does not guarantee an accurate fit. Prepolymerise each layer for 10 sec. with a hand-held light-curing unit. After the build-up is complete, it is fully polymerised for 40 sec.
Important: With a **multilayered build-up** do not remove the inhibition film on the surface; this film ensures an optimum bond of the different layers and prevents stresses in the modelling resin.
Adding on: If material has to be added to the finished build-up, e.g. after trimming with rotary instruments, ensure that the core is free of dirt and grease before applying additional **Conlight**.
The inhibition film is removed from the surface with rotary instruments or acetone only after the post and core is finally finished.

Casting recommendation

The post and core can be invested and cast in the usual way. The preheat furnace should be heated as follows:

0-280 °C:	Heat rate 8°C/min.
at 280°C:	Hold time 20 min.
280-580°C:	Heat rate 8°C/min.
at 580°C:	Hold time 20 min.
580-final temperature:	Heat rate 8°C/min.
Final temperature:	According to the type of alloy / 60 min. hold time

Warning

Conlight should not come into contact with the mucosa and the eyes or remain permanently in the mouth. Wear protective gloves, protective clothing and eye protection. Those sensitive to the product may experience sensitisation. We recommend discontinuing use in such cases. Switch on aspirator when grinding. Harmful to aquatic life with long lasting effects.

Contraindications, Interactions

The use of the product is contraindicatited if known allergy to any ingredient exists. Interactions are not determined.

Secondary effects

Product may cause allergic reaction.

Storage

Store at 4-25°C.
Protect **Conlight** syringes from heat and sunlight.
Do not use after the expiry date.

Disposal instructions:

Dispose of contents/ container in accordance with local regulation.

Pack contents

3 x 3 g **Conlight** slide syringe
9 Application tips

Manufacturer:
DeltaMed
DeltaMed GmbH
Raiffeisenstraße 8a
D-61169 Friedberg
Phone. +49 (0) 6031-7283-0
Fax +49 (0) 6031-7283-29
info@deltamed.de
www.deltamed.de

CE 0124

This product was developed for use in dentistry and should be used according to the instructions for use. The manufacturer does not accept liability for damage caused by its use for any other purpose. The user is also personally responsible for checking before use that the material is suitable and can be used for the intended purpose, particularly if this is not listed in the instructions for use.

Version 04, Creation date: 11.05.2015

Legend

LOT	Lot number		Recommended storage temperature
	Expiry date		Manufacturer
	Read instructions for use		Protect from sunlight

APPENDIX C

GC pattern™; GC Corp – Instructions for use

Prior to use, carefully read the instructions for use

GB

PATTERN RESIN LS

ACRYLIC RESIN FOR PATTERNS

For use only by a dental pr ofessional in the recommended indications.

RECOMMENDED INDICATIONS

(1) To make the pattern of:
* tapered coping for telescopic crowns and other telescope crowns.
* inlay, palatal and lingual bar, connector and clasp.
* Maryland bridge.

(2) Temporary splint for soldering.
(3) In the mouth for core build up pattern.
(4) Construction of implant superstructures.

CONTRAINDICATIONS

In susceptible individuals, sensitisation to the pr oduct cannot be excluded. Use of the pr oduct should be discontinued if allergic reactions are observed.

WARNING

Contains methyl methacrylate. When used dir ectly in the mouth for core build up particular care should be taken to avoid contact with the skin or oral mucosa. In case of accidental contact, immediately remove the of fending material and flush the surrounding area liberally with water.

DIRECTIONS FOR USE

1. **Powder and liquid preparation**
   Dispense adequate amounts of powder and liquid into each rubber cup (Fig. 1).
2. **Building the coping (for secondary crown patterns of tapered crowns or telescopic crowns)**
   a) Moisten the tip of the brush with the liquid and pick up a small amount of powder (Fig. 2).
   b) Deposit this mixtur e on the crown and pr o-gressively build up the secondary crown pattern by repeating the pr oce-dure (Fig. 3).
   - In this case, no sepa-rating medium is required, but when work-ing on a stone model, GC Acro Sep, GC Multi-Sep or V aseline should be used as separator.
   - Clean the brush with liquid after use or during the work if necessary.
3. **Checking the internal surface of the pattern**
   After the resin has set (3 min. at 23°C/73° F), remove the pattern care-

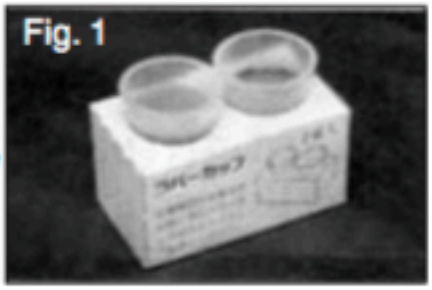
Fig. 1

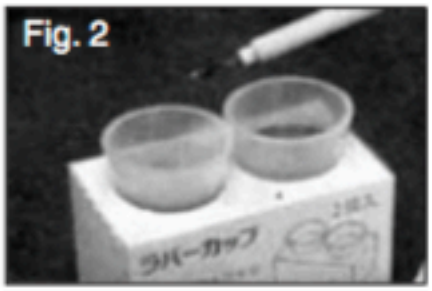
Fig. 2

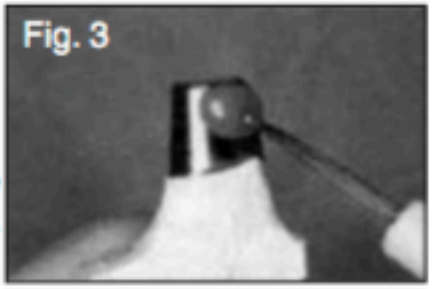
Fig. 3

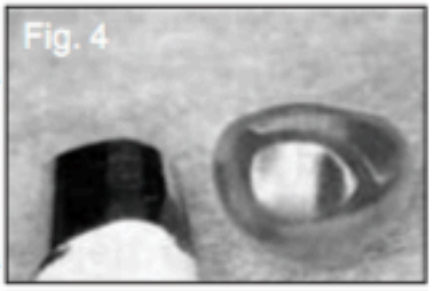
Fig. 4

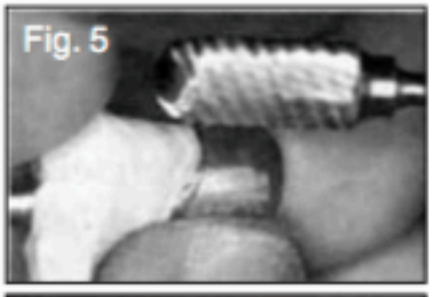
Fig. 5

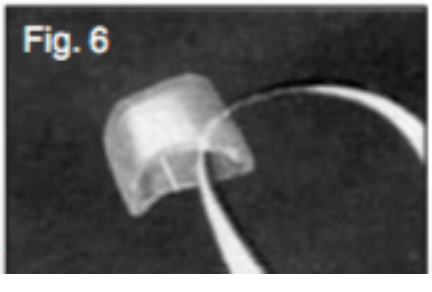
Fig. 6

fully from the inter nal crown and check the margin and the inter nal surface (Fig. 4).

4. **Fine adjustment**
   a) Return the patter n to the internal crown and make a uniform thickness (0.3-0.4 mm) by using a bur (Fig. 5).
   b) Remove the patter n and check the thickness with the measuring device (Fig. 6).

5. **Waxing veneer and Cut out**
   a) Perform the wax-up with inlay wax (Fig. 7).
   Note: There is no need to clean the surface of the pattern resin with a cleaning agent befor e waxing.
   b) Cut out the veneer for the facing (Fig. 8).
   c) Place the r etention beads (Fig. 9).

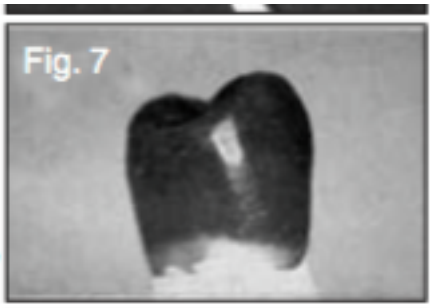
Fig. 7


Fig. 8

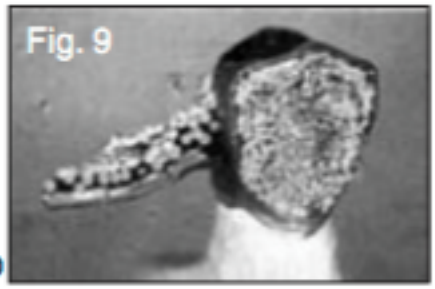
Fig. 9

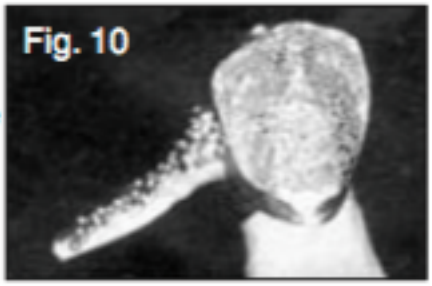
Fig. 10

6. **Investing, Burning out and Casting**
   For a single cr own, all pr ocedures can be performed in the usual manner. For a larger pattern, hold at 250°C (482°F) for 1 hour before raising to the final burn out temperature (Fig. 10).

STORAGE

Store in a cool place away from direct sunlight.
(Shelf life: 5 years from date of manufacture).

NOTES

1. Do not mix with other chemically cured resins.
2. Do not return the residual powder and liquid to the bottle.
3. In case of contact with skin wash off with soap and water.

PACKAGES

1. Powder : 100g, 1 kg
2. Liquid : 100g (105mL), 250g (262mL)
3. 1-1 pkg : 100g powder, 100g (105mL) liquid with accessories

CAUTION

1. The liquid is highly FLAMMABLE. Avoid sources of ignition.
2. In case of contact with eyes, flush immediately with water and seek medical attention.

APPENDIX D

Panasil® Putty Soft, and Initial Contact Light; Kettenbach® – Instructions for use

Directions For Use

KETTENBACH®

Panasil®

Vinyl Polysiloxane Impression Material ISO 4823

Made in Germany
37286/3808

CE

Directions for use **English**

KETTENBACH®

Panasil® binetics putty fast
Panasil® binetics putty soft
Panasil® putty
Panasil® putty fast set
Panasil® putty soft
Panasil® tray fast heavy
Panasil® tray soft heavy
Panasil® tray soft heavy fast
Panasil® monophase medium
Panasil® initial contact regular
Panasil® initial contact regular fast
Panasil® contact two in one light
Panasil® initial contact light
Panasil® initial contact light fast
Panasil® contact plus x-light
Panasil® initial contact x-light
Panasil® initial contact x-light fast

Manufacturer:
Kettenbach GmbH & Co. KG
Im Heerfeld 7
35713 Eschenburg, Germany
www.kettenbach.com

Distributed in the U.S. by:
Kettenbach LP
7777 Center Avenue, Suite 280
Huntington Beach, CA 92647, USA

Vinyl Polysiloxane Impression Material ISO 4823

Made in Germany
37286/3808

CE

For professional use only. Caution: Federal (U.S.A.) Law restricts this device to sale by or on the order of a dentist.

Vinyl Polysiloxane Impression Material ISO 4823

Product Description

Panasil impression materials are addition-curing, elastomeric materials with hydrophilic properties, high tear strength, dimensional accuracy, and a high resistance to permanent deformation. Panasil initial contact displays a high initial hydrophilicity.

The Panasil family consists of five different viscosities (putty, heavy-bodied, medium-bodied, light-bodied, x-light-bodied), available in an assortment of delivery systems: standard 1:1 50 ml automix cartridges, 5:1 362 ml foil bags for use in most automatic dispensing and mixing systems, and traditional 1:1 putty jars.

Indications/Techniques

Panasil® putty (putty, putty fast set, putty soft) and Panasil® binetics putty (putty fast, putty soft) are to be used as preliminary materials for:

- Two-step putty-wash impression technique
- One-step putty-wash impression technique
- Two-step putty-wash impression technique using a foil (plastic putty spacer)
- One-step putty impression technique for forming functional peripheries

Panasil® tray fast, Panasil® tray soft and Panasil® tray soft fast are to be used as heavy-bodied materials for:

- One-step impression technique (simultaneous technique) using single or dual viscosities
- Two-step impression technique using dual viscosities
- Functional impressions

Panasil® monophase is to be used as a medium-bodied tray or syringeable impression material for:

- Taking impressions over fixed/removable restorations and implants (i.e., transferring impression posts and bridge components)
- Functional impressions
- Fabricating crown and bridgework or inlays

- Fabricating full or partial dentures
- Reline impressions
- Use in the simultaneous mixing technique as well as the putty-wash and triple tray techniques
- Transferring root posts when fabricating posts and cores indirectly

Panasil® contact plus, Panasil® contact two in one and Panasil initial contact are to be used as syringeable impression materials for:

- Two-step putty-wash impression technique
- One-step putty-wash impression technique
- One-step impression technique using a foil (plastic putty spacer)
- One-step impression technique (simultaneous technique) using dual viscosities
- Reline impressions
- Fabricating full or partial dentures

Warnings

Do not use Panasil impression materials as a temporary reliner.

Do not use Panasil impression materials with condensation-curing silicones, polyether or polysulfide materials.

Panasil putty impression materials are not suitable for detailed impressions when used alone.

Cautions

Do not use after expiration date.

Do not leave any residual impression material in the sulcus or oral cavity.

Do not swallow impression material! If swallowed: consult a medical doctor if problems arise or persist.

Avoid contact with eyes. If accidental contact with the eyes occurs, rinse immediately and thoroughly with an eye wash or water. Consult a medical doctor if problems arise or persist.

The product does not normally cause allergic reactions. However, for sensitive persons, an allergic reaction to the product cannot be ruled out.

Use of products containing active sulfur, aluminium chloride or nitrogen compounds (retraction cords containing ferric sulfate, polysulfide impression materials, etc.) in conjunction with this product will

interfere with the setting reaction of the vinyl polysiloxane material. Use of the materials requires the area to be rinsed thoroughly to remove all residue, before an impression is taken. Do not use latex gloves.

Do not interchange the base and hardener lids or scoops for hand-mixed jar putty.

In order to ensure an optimal adhesion of the two materials during the two-step putty-wash impression technique, both impression steps must take place one immediately after the other.

Before fitting the dynamic mixer, dispense material until equal amounts of base and catalyst appear; wipe excess. Firmly place dynamic mixer and lower locking lever.

When taking impressions of areas with severe undercuts and wide interdental spaces, use standard block-out techniques.

When using a custom impression tray, ensure that sufficient space remains between the side of the tray and the teeth/jaw.

Do not allow the material to enter the sewer or water system to avoid environmental contamination.

Avoid contact with clothing, since the material cannot be removed by dry cleaning.

Product Overview

Product name	ISO 4823	Consistency (approx.) mm	Mixing ratio and total content volume per unit	Mixing technique	Mixing element
Panasil® binetics putty fast	Type 0, Putty	23	5:1, 362 ml in foil bags	Plug & Press® Dispenser or other automatic dispensing and mixing system	dynamic mixer
Panasil® binetics putty soft	Type 0, Putty	23	5:1, 362 ml in foil bags	Plug & Press® Dispenser or other automatic dispensing and mixing system	dynamic mixer
Panasil® putty	Type 0, Putty	24	1:1, 900 ml in jars	manual, 1 scoop (12.3 ml) per component (Base & Hardener)	hand mix
Panasil® putty fast set	Type 0, Putty	24	1:1, 900 ml in jars	manual, 1 scoop (12.3 ml) per component (Base & Hardener)	hand mix
Panasil® putty soft	Type 0, Putty	24	1:1, 900 ml in jars	manual, 1 scoop (12.3 ml) per component (Base & Hardener)	hand mix
Panasil® tray fast heavy	Type 1, Heavy-bodied	32	5:1, 362 ml in foil bags	Plug & Press® Dispenser or other automatic dispensing and mixing system	dynamic mixer
Panasil® tray fast heavy	Type 1, Heavy-bodied	32	1:1 50 ml cartridge	Applyfix® 4 dispensing gun DS-50 1:1/2:1	static green mixing tip MB Ø 6.5 mm
Panasil® tray soft heavy	Type 1, Heavy-bodied	32	5:1, 362 ml in foil bags	Plug & Press® Dispenser or other automatic dispensing and mixing system	dynamic mixer
Panasil® tray soft heavy	Type 1, Heavy-bodied	32	1:1 50 ml cartridge	Applyfix® 4 dispensing gun DS-50 1:1/2:1	static green mixing tip MB Ø 6.5 mm
Panasil® tray soft heavy fast	Type 1, Heavy-bodied	32	5:1, 362 ml in foil bags	Plug & Press® Dispenser or other automatic dispensing and mixing system	dynamic mixer
Panasil® tray soft heavy fast	Type 1, Heavy-bodied	32	1:1 50 ml cartridge	Applyfix® 4 dispensing gun DS-50 1:1/2:1	static green mixing tip MB Ø 6.5 mm

Product Overview

Product name	ISO 4823	Consistency (approx.) mm	Mixing ratio and total content volume per unit	Mixing technique	Mixing element
Panasil® monophase medium	Type 2, Medium-bodied	35	5:1, 362 ml in foil bags	Plug & Press® Dispenser or other automatic dispensing and mixing system	dynamic mixer
Panasil® monophase medium	Type 2, Medium-bodied	35	1:1 50 ml cartridge	Applyfix® 4 dispensing gun DS-50 1:1/2:1	static green mixing tip MB Ø 6.5 mm
Panasil® initial contact regular	Type 2, Medium-bodied	37	1:1 50 ml cartridge	Applyfix® 4 dispensing gun DS-50 1:1/2:1	static green mixing tip MB Ø 6.5 mm
Panasil® initial contact regular fast	Type 2, Medium-bodied	37	1:1 50 ml cartridge	Applyfix® 4 dispensing gun DS-50 1:1/2:1	static green mixing tip MB Ø 6.5 mm
Panasil® contact two in one light	Type 3, Light-bodied	38	1:1 50 ml cartridge	Applyfix® 4 dispensing gun DS-50 1:1/2:1	static green mixing tip MB Ø 6.5 mm
Panasil® initial contact light	Type 3, Light-bodied	41	1:1 50 ml cartridge	Applyfix® 4 dispensing gun DS-50 1:1/2:1	static yellow mixing tip MB Ø 4.2 mm
Panasil® initial contact light fast	Type 3, Light-bodied	41	1:1 50 ml cartridge	Applyfix® 4 dispensing gun DS-50 1:1/2:1	static yellow mixing tip MB Ø 4.2 mm
Panasil® contact plus x-light	Type 3, Light-bodied	42	1:1 50 ml cartridge	Applyfix® 4 dispensing gun DS-50 1:1/2:1	static yellow mixing tip MB Ø 4.2 mm
Panasil® initial contact x-light	Type 3, Light-bodied	44	1:1 50 ml cartridge	Applyfix® 4 dispensing gun DS-50 1:1/2:1	static yellow mixing tip MB Ø 4.2 mm
Panasil® initial contact x-light fast	Type 3, Light-bodied	44	1:1 50 ml cartridge	Applyfix® 4 dispensing gun DS-50 1:1/2:1	static yellow mixing tip MB Ø 4.2 mm

Technical Data

Product name	Mixing ratio	Working time at 23° C/ 74° F ≤	Working time at 35° C/ 95° F ≤	Intraoral setting time at 35° C/ 95° F ≥	Total setting time* ≥	Hardness (approx.) Shore	Linear dimensional change (approx.) %	Elastic-Recovery test (approx.) %	Strain in compression (approx.) %
Panasil® binetics putty fast	5:1	1 minute 30 seconds	not applicable	2 minutes 30 seconds	4 minutes	A 63	– 0.20	99.5	2.5
Panasil® binetics putty soft	5:1	2 minutes	not applicable	3 minutes	5 minutes	A 56	– 0.20	99.5	3.5
Panasil® putty	1:1	2 minutes	not applicable	2 minutes	4 minutes	A 66	– 0.20	99.0	2.7
Panasil® putty fast set	1:1	1 minute 30 seconds	not applicable	2 minutes	3 minutes 30 seconds	A 66	– 0.20	99.0	2.7
Panasil® putty soft	1:1	2 minutes	not applicable	2 minutes	4 minutes	A 60	– 0.20	99.0	2.7
Panasil® tray fast heavy	5:1	1 minute 20 seconds	not applicable	2 minutes	3 minutes 20 seconds	A 62	– 0.20	99.7	2.5
Panasil® tray fast heavy	1:1	1 minute	not applicable	2 minutes	3 minutes	A 62	– 0.20	99.5	3.0
Panasil® tray soft heavy	5:1	2 minutes	not applicable	2 minutes	4 minutes	A 55	– 0.20	99.7	3.0
Panasil® tray soft heavy	1:1	2 minutes	not applicable	2 minutes	4 minutes	A 55	– 0.20	99.5	3.0
Panasil® tray soft heavy fast	5:1	1 minute 20 seconds	not applicable	2 minutes	3 minutes 20 seconds	A 55	– 0.20	99.5	3.0
Panasil® tray soft heavy fast	1:1	1 minute	not applicable	2 minutes	3 minutes	A 55	– 0.20	99.5	3.0

*Total setting time (removal time from mouth) from start of mix.

Technical Data

Product name	Mixing ratio	Working time at 23° C/ 74° F ≤	Working time at 35° C/ 95° F ≤	Intraoral setting time at 35° C/ 95° F ≥	Total setting time* ≥	Hardness (approx.) Shore	Linear dimen-sional change (approx.) %	Elastic-Recovery test (approx.) %	Strain in com-pression (approx.) %
Panasil® monophase medium	5:1	2 minutes	1 minute	2 minutes	4 minutes	A 58	– 0.20	99.7	3.0
Panasil® monophase medium	1:1	2 minutes	1 minute	2 minutes	4 minutes	A 58	– 0.20	99.7	3.5
Panasil® initial contact regular	1:1	1 minute 30 seconds	1 minute	2 minutes 30 seconds	4 minutes	A 46	– 0.20	99.7	3.0
Panasil® initial contact regular fast	1:1	1 minute	30 seconds	2 minutes	3 minutes	A 46	– 0.20	99.7	3.0
Panasil® contact two in one light	1:1	2 minutes	1 minute	2 minutes	4 minutes	A 46	– 0.20	99.7	5.0
Panasil® initial contact light	1:1	1 minute 30 seconds	1 minute	2 minutes 30 seconds	4 minutes	A 46	– 0.20	99.3	3.5
Panasil® initial contact light fast	1:1	1 minute	30 seconds	2 minutes	3 minutes	A 46	– 0.20	99.3	3.5
Panasil® contact plus x-light	1:1	2 minutes	1 minute	2 minutes	4 minutes	A 46	– 0.20	99.7	3.5
Panasil® initial contact x-light	1:1	1 minute 30 seconds	1 minute	2 minutes 30 seconds	4 minutes	A 46	– 0.20	99.3	3.5
Panasil® initial contact x-light fast	1:1	1 minute	30 seconds	2 minutes	3 minutes	A 46	– 0.20	99.3	3.5

*Total setting time (removal time from mouth) from start of mix.

Note

To ensure optimal impressions, the temperature of the material should not deviate from 23° C (74° F) before applying. Otherwise, working and setting times will be affected.

Impression tray: Preparation and adhesives

In principle, all common impression trays can be used if a relevant dynamic pressure is guaranteed. When retention is not sufficient, ensure a strong bond to the impression material, by brushing the impression tray with a thin film of Panasil adhesive* for addition-curing silicone prior to loading the tray with impression material. Allow to dry per manufacturer's instructions.

Instructions for use: Jar material for hand-mix putty preparation

Only use materials with the same lot number.

Do not interchange the base and hardener lids or scoops.

Use the scoops to dispense equal amounts of base and hardener paste.

The different color scoops must only be used for the materials with corresponding colors.

Close the containers carefully after use, and ensure that the lids are not interchanged.

Contamination of base paste with hardener paste in the container renders the material unusable.

Knead the base paste and hardener paste for 45 seconds until the material is homogeneously colored.

Should gloves be worn, test them for compatibility prior to mixing with a sample of the material to be mixed. Certain types of gloves (such as latex) can prevent the polymerization. Using vinyl gloves is recommended.

Prior to taking the wash impression, the preliminary impression must be cleaned with water, dried and trimmed using standard methods.

Foil bag material for use in most automatic dispensing and mixing systems

Before using the base material for the first time, remove the white safety pin from the activating head of the large foil bag by turning it in the direction of the arrow and pulling it out (Figure 1).

Place the large foil bag with the integrated activating head in the cartridge body. Ensure that the notches on the activating head and cartridge case are aligned (Figure 2).

Firmly press the activating head into the final position on the cartridge body. The foil bag is automatically pierced by a pin when the activating head is pressed down (Figure 3).

Follow the same procedure as in Figure 2 and 3 for the catalyst material. (Note: There is no safety pin on the catalyst foil bag.)

Instructions for use of Kettenbach's automatic dispensing and mixing system (Plug & Press® Dispenser) in combination with Kettenbach's dynamic mixer

Use only Kettenbach dynamic mixers to ensure optimum performance. If not using a Kettenbach Plug & Press Dispenser, please follow the manufacturer's instructions for your automatic dispensing and mixing system.

- Move the plungers to the top by turning the control knob (Figure 4).
- Insert the cartridge body into the unit (Figure 5).
- Turn the control knob to move the plungers into the cartridge body, and continue turning until the plungers come into contact with the foil bags (Figure 6).
- Once there is contact, press one of the two start keys (at the front on top of the unit) to dispense the material (Figure 7).

- Before fitting the dynamic mixer, dispense material until equal amounts of base and catalyst appear (Figure 7); wipe excess. Firmly place dynamic mixer (Figure 8) and lower locking lever.

Load the tray with the required amount of material. Hold the impression tray at an angle and press lightly against the tray. Leave the dynamic mixer in the material while dispensing (Figure 9). Leave the filled dynamic mixer on the cartridge body as a seal.

Before next use, release the locking clip to remove the used dynamic mixer and check that the outlets in the activating heads are not blocked. Fit a new dynamic mixer, lower locking lever and continue as usual.

When finished, simply remove the empty foil bags and activating heads from the cartridge body and discard them. The cartridge body is reusable (Figure 10). The activating heads are disposable.

Cartridge material for use in Applyfix® 4 dispensing gun DS-50 1:1/2:1

Insert the cartridge into the Applyfix 4 dispensing gun DS-50 1:1/2:1. Ensure that the notches on the cartridge base are pointing down. The clasp will not close if the cartridge is not properly inserted into the dispensing gun.

Remove the cartridge cap. The cap can be replaced after initial use.

Insert plunger into cartridge and dispense a small amount of impression material until equal amounts are dispensed at the same rate.

Install a mixing tip on the cartridge, and turn cap 90 degrees clockwise to lock in place.

Inject the required amount of material, directly into the tray or the preliminary impression, or into a delivery syringe. To apply the material around the prepared teeth, use the delivery syringe or the cartridge with an intraoral tip on the mixer. Check to ensure materials are set prior to mouth removal.

Leave used mixing tip on the cartridge after use or replace the cartridge cap.

Before using the cartridge again, remove cartridge cap or remove and discard the used mixing tip. Check the cartridge openings to ensure no polymerized material is present. Should this be the case, unblock the openings and dispense a small amount of impression material until equal amounts are dispensed at the same rate.

Install a new mixing tip and continue as described above.

The Applyfix 4 dispensing gun DS-50 1:1/2:1 can be sterilized in the autoclave.

Storage conditions:

Store in a dry place at 18°–25° C (64°–77° F). Keep away from sunlight.

Disinfection:

Impressions can be disinfected using for example, a 2% acidic glutaraldehyde solution. Use disinfection solutions specific for impression materials (e.g., Silosept*). See manufacturer instructions.

Electroplating:

Impressions may be silver-plated with an alkaline-plating solution only.

Pouring the impressions:

For model fabrication, do not pour the impression until one hour after disinfection. Impressions can also be poured within two weeks with standard dental stone class IV (e.g., Tewestone* or Tewerock*).

Trademarks*

Kettenbach, Applyfix® 4, Panasil®, Silosept®, Tewerock®, Tewestone® and Plug & Press® Dispenser are registered trademarks of Kettenbach GmbH & Co. KG.

*Note

Selected Kettenbach materials are available in certain markets only.

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Legend

Medical device	CE	Use by	
Temperature limitation		Keep dry	
Keep away from sunlight		Catalog number	REF
Batch code	LOT	Caution, consult accompanying documents	
Dual system (Germany only)		Diameter	Ø
Cartridge		Static mixing tip MB	
Mixing tip Type B	MB	Intraoral tip	
Scoop		Jar	
Cartridge body		Foil bags	
Dynamic mixer		Rx only For professional use only. Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a dentist.	
Millimeter	mm	Milliliter	ml
Less than or equal to	≤	Greater than or equal to	≥

Panasil®

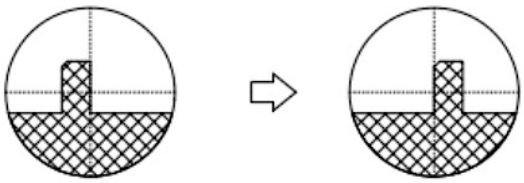
APPENDIX E

Mitutoyo Toolmaker's Microscope – Instructions for measurement

3.2 Measurement

3.2.1 Dimensional measurement

Align a measuring point on the workpiece with one of the cross-hairs and take the reading from the Micrometer Head. Then, move the XY stage by turning the Micrometer Head and align another measuring point with the same cross-hair and take the reading at this point. The difference between the two readings represents the dimension between the two measuring points.



A Digimatic Head and Digital Counter can be used, in place of the Micrometer Head, for digital display of the displacement. They also eliminate reading errors. Since the zero-set button zeroes the counter at any position, the displacement can be read directly.

Figure 18 **- Measurement procedure according to user's manual - Mitutoyo Toolmaker's Microscope.**

APPENDIX F

Measurements obtained on Microscope Analysis

Table 9

Measurements of the Vertical Gaps in mm – Group A (photopolymerizing)

	Implant Analog 2				Implant Analog 3				Implant Analog 4			
	B	L	M	D	B	L	M	D	B	L	M	D
P.1	0,004	0,009	0,01	0,009	0,004	0,008	0,01	0,011	0,01	0,004	0,004	0,005
P.2	0,011	0,013	0,011	0,017	0,016	0,008	0,014	0,016	0,009	0,012	0,007	0,006
P.3	0,007	0,004	0,008	0,006	0,012	0,004	0,004	0,01	0,018	0,008	0,003	0,014
P.4	0,009	0,015	0,004	0,009	0,016	0,017	0,014	0,011	0,012	0,02	0,014	0,014
P.5	0,02	0,012	0,011	0,019	0,034	0,019	0,026	0,023	0,056	0,069	0,061	0,089
P.6	0,014	0,012	0,014	0,015	0,016	0,004	0,013	0,015	0,01	0,009	0,007	0,007
P.7	0,006	0,007	0,008	0,003	0,013	0,004	0,005	0,014	0,007	0,007	0,008	0,001
P.8	0,003	0,003	0,004	0,004	0,006	0,003	0,004	0,004	0,007	0,003	0,004	0,005
P.9	0,004	0,008	0,007	0,006	0,004	0,006	0,008	0,007	0,007	0,004	0,003	0,005
P.10	0,007	0,004	0,007	0,007	0,0011	0,003	0,003	0,01	0,0017	0,007	0,003	0,013
Mean	0,0085	0,0087	0,0084	0,0095	0,01221	0,0076	0,0101	0,0121	0,01377	0,0143	0,0114	0,0159
Max	0,02	0,015	0,014	0,019	0,034	0,019	0,026	0,023	0,056	0,069	0,061	0,089
Min	0,003	0,003	0,004	0,003	0,0011	0,003	0,003	0,004	0,0017	0,003	0,003	0,001

Table 10

Measurements of the Vertical Gaps in mm – Group B (autopolymerizing)

	Implant Analog 2				Implant Analog 3				Implant Analog 4			
	B	L	M	D	B	L	M	D	B	L	M	D
A.1	0,012	0,012	0,011	0,015	0,023	0,02	0,03	0,029	0,101	0,05	0,042	0,047
A.2	0,03	0,024	0,017	0,025	0,09	0,12	0,106	0,095	0,078	0,04	0,11	0,15
A.3	0,017	0,026	0,012	0,03	0,06	0,042	0,07	0,06	0,03	0,017	0,016	0,02
A.4	0,018	0,026	0,013	0,04	0,06	0,05	0,06	0,06	0,04	0,02	0,019	0,022
A.5	0,018	0,03	0,017	0,031	0,043	0,036	0,047	0,05	0,04	0,05	0,021	0,023
A.6	0,018	0,034	0,018	0,023	0,022	0,027	0,018	0,033	0,062	0,07	0,055	0,051
A.7	0,0133	0,013	0,0127	0,0163	0,025	0,022	0,034	0,034	0,012	0,051	0,119	0,158
A.8	0,024	0,033	0,03	0,03	0,05	0,049	0,043	0,048	0,029	0,018	0,024	0,026
A.9	0,017	0,033	0,015	0,036	0,031	0,022	0,058	0,06	0,043	0,021	0,02	0,025
A.10	0,019	0,03	0,017	0,031	0,052	0,039	0,049	0,053	0,047	0,04	0,032	0,049
Mean	0,01863	0,0261	0,01627	0,02773	0,0456	0,0427	0,0515	0,0522	0,0482	0,0377	0,0458	0,0571
Max	0,03	0,034	0,03	0,04	0,09	0,12	0,106	0,095	0,101	0,07	0,119	0,158
Min	0,012	0,012	0,011	0,015	0,022	0,02	0,018	0,029	0,012	0,017	0,016	0,02

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